REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1, 3, 6, 8, 11-13, 15, 18-26, and 73 are pending with entry of this amendment, claims 2, 4-5, 7, 9-10, 14, 16-17, and 27-72 being cancelled. These cancellations are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Claims 1, 3, 6, 8, 13, 15, 18-19, 21-24, and 73 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claims 1, 3, 6, 8, 13, 15, 18, 19, 22, and 24, support for the change to "IL-27R agonist" as opposed to a ligand to "IL-27-R/WSX-1"can be found throughout the specification. For example, the specification describes, at the second full paragraph on page 10, the terms used to refer to a receptor for IL-27. In addition, the use of the term "agonist" finds support in original claims, e.g., claim 2 where the ligand is described as an agonist. With respect to claims 21, 23, and 73, minor amendments are made to correct typographical errors. In addition to the above amendment, claim 1 is also further clarified by specifying that a patient in need of immune suppression is selected for administration of the agonist. This adds no new matter as immune suppression is discussed throughout the specification and claims as originally filed, e.g., as in original claim 2.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

The Election/Restriction Requirement.

Pursuant to a restriction requirement made final, Applicants cancel claims 27-72 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

The Information Disclosure Statement.

Applicants note with appreciation the Examiner's thorough consideration of the references cited in the Information Disclosure Statement (Form 1449) submitted on September 8, 2006.

The Priority Claim is Proper

Benefit of the filing dates of provisional application 60/444,494, filed January 31, 2003, and provisional application 60/519,074, filed November 10, 2003, was not acknowledged by the Examiner. As described in detail below Applicants have presented a proper priority claim to both documents and respectfully request that the relevant priority claims be properly acknowledged.

Provisional application 60/444,494 was filed on January 31, 2003 and the present application was filed on February 2, 2004. 35 U.S.C. §119(e)(3) specifically states that "if the day that is 12 months after the filing date of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, the period of pendency of the provisional application shall be extended to the next succeeding secular or business day." For USSN 60/444,494, the "day that is 12 months after the filing date," January 31, 2004 was a Saturday, so the pendency of this provisional application was extended to the next succeeding business day, February 2, 2004. Therefore, an application filed on February 2, 2004 may correctly claim benefit of USSN 60/444,494.

In addition, M.P.E.P § 201.04(b) provides an example, "if a provisional application was filed on January 15, 1999, the last day of pendency of the provisional application under 35 U.S.C. 111(b)(5) and 35 U.S.C. 119(e)(3) is extended to January 18, 2000 (January 15, 2000 is a Saturday and Monday, January 17, 2000 is a Federal holiday and therefore, the next succeeding business day is Tuesday, January 18, 2000). A nonprovisional application claiming the benefit of the provisional application must be filed no later than January 18, 2000." This makes it entirely clear that the present application may properly claim the benefit of provisional application 60/444,494.

Regarding Provisional Application 60/519,074, the Examiner has not given the instant application the benefit of the earlier filing date, November 10, 2003, because the provisional application allegedly does not correspond to the scope of the claims in the instant application. Applicants respectfully traverse. As the scope of the claim is changed herein, Applicants respectfully request that the Examiner reconsider priority for the provisional application; Applicants further respectfully assert that the scope of the claims as amended is

taught and enabled by the provisional application. For example, the inventive concept that the receptor for IL-27 is involved in control of the duration and intensity of immune responses in mammals is provided, e.g., on the 2nd column on page 10, where the role of WSX-1 is described and proposed as a novel target for immune suppression.

Objections to the Specification

The specification was objected to for alleged lack of trademarks and blocks in the text on page 106. Applicants amend the specification herein to correct these errors and omissions. No new matter is added with these amendments as they merely add trademark symbols and correct typographical errors that left boxes in place of centigrade symbols. Applicants respectfully point out that some of the terms for which trademarks were requested by the Examiner are company names, as opposed to products, and do not require trademarks. Applicants respectfully request that the amendments be entered and the objection be withdrawn.

Objections to the Claims

The claims were objected to for alleged confusion regarding the terms "IL-27/WSX-1" and "IL-27R/WSX-1." Applicants amend herein to replace "IL-27R/WSX-1" with "IL-27R" and respectfully point out that the terms are defined in the specification. For example, in the second full paragraph on page 10 "IL-27R/WSX-1" is defined as one of several terms, in addition to "IL-27R" and "WSX-1," that are used to refer to a receptor for IL-27. On the last paragraph on page 1, the specification makes clear that "IL-27/WSX-1" refers to a ligand/receptor pair, i.e., both the IL-27 ligand and the receptor WSX-1. The terms are used consistently in this manner throughout the specification and examples.

However, to expedite prosecution, Applicants herein amend the claims to refer to IL-27R. Consistent with the specification, this term is used to refer to a receptor for IL-27. Although the specification uses various terms to refer to the receptor for IL-27, it specifies, e.g., in the first full paragraph on page 3, that IL-27R refers to the heterodimeric receptor comprising WSX-1 and IL-27RPP. Applicants submit that the terms are not confusing as expressed in the claims and Applicants respectfully request that the objection be withdrawn.

Claims 21, 23, and 73 were objected to for misspellings. Applicants amend

herein to correct errors in spelling as suggested by the Examiner. Applicants therefore respectfully request that all remaining objections to the claims be withdrawn.

35 U.S.C. §112, First Paragraph – The Claims are Enabled.

Claims 1-26 and 73 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. First, the Examiner alleged that the claims are not enabled for the prevention of an immune disorder; and second, that the claims are not enabled because they allegedly do not enable one of skill in the art to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse in part and amend in part.

The claims are amended herein to clarify that the method is used to treat any patient in need of immune suppression, e.g., including a step of "selecting a patient in need of immune suppression" and to refer specifically to the use of an agonist of IL-27R for said immune suppression.

To be an enabling disclosure under § 112, first paragraph, a patent must contain a description that enables one skilled in the art to make and use the claimed invention. That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive. *See* In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Whether undue experimentation is required by one skilled in the art is typically determined by reference to eight factors considered relevant to the inquiry: (1) quantity of experimentation necessary; (2) amount of guidance presented; (3) presence of working examples; (4) nature of the invention; (5) state of the prior art; (6) relative skill of those in the art; (7) predictability of the art; and (8) breadth of the claims. *See id.*

The Examiner addressed each of these factors and came to a conclusion that the claims are not sufficiently enabled for their scope. The Examiner acknowledged that the relative skill of those in the art is high and the state of the prior art is high. Applicants concur on the level of skill and state of the art. However, the Examiner alleged that the level of guidance provided is low and that the breadth of the claims is too large. Applicants amend in part and traverse in part. Applicants herein amend the claims to cover treating patients in

need of immune suppression as opposed to modulating or preventing an immune disorder. Applicants respectfully disagree with the rejection for the reasons set forth below.

Regarding quantity of experimentation necessary and nature of the invention, Applicants believe that the Examiner may actually be concerned with utility of the invention and refer to *In re Brana,* which discussed the issue of enablement of a pharmaceutical invention under a 35 U.S.C. §112, first paragraph rejection where the issue was primarily one of utility. Applicants apply the Federal Circuit's standard from *In re Brana* to this rejection. As stated by the Federal Circuit, in *In re Brana* 34 U.S.P.Q.2d 1436 (Fed.Cir. 1995), "the stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." It further quotes *In re Krimmel*, 130 U.S.P.Q. 215 (CCPA 1961) as stating that "one who has taught the public that a compound exhibits some desirable pharmaceutical property in a standard experimental animal has made a significant and useful contribution to the art . . . ." In the present case, the compounds used in the claimed methods may not have been used in humans to suppress the immune system, but the mouse models that were used show that a lack of WSX-1 results in an uncontrolled immune response, e.g., that IL-27R is involved in immune activation/suppression and that an agonist ligand that binds to IL-27R is useful in suppressing the immune system. The Examples in the specification provide copious data to prove this connection. The desirable pharmaceutical property taught by Applicants is that immune suppression and/or activation is achieved by the activation or deactivation of the IL-27 receptor. Therefore, when considering the relative skill of those in the art, the breadth of the claims, and the state of the prior art, one of skill would know how to use this desirable property taught by Applicants to suppress the immune system in a patient in need thereof. Therefore, the claims are enabled for their scope and Applicants respectfully request that the rejection be withdrawn.

In addition, the Examiner alleged that the guidance in the specification was applicable only to conditions such as *Toxoplasma gondii* and *T. muris* infections and that undue experimentation would be required to determine whether an agonist of WSX-1 could be used to treat or prevent an immune disorder. As required by *In re Brana* and described above, Applicants have demonstrated the importance of the IL-27 receptor for suppression of the immune system in mice, a standard experimental animal. The guidance provided

regarding the use of a ligand to IL-27R is readily applicable to any condition in which suppression of the immune system is desired. As an illustration, see, e.g., a recent advance online publication in Nature Medicine by Obi et al. (published online 13 May 2007) describing the role of IL-27 in human uveitis and scleritis. The publication makes clear that the claimed invention has applicability in other systems. While some experimentation would be required to determine if the method is useful in a particular disorder or a particular system, the experimentation is not considered undue, e.g., under the standards provided in *Brana*. The claims are enabled for the use of an IL-27R agonistic ligand in immune suppression and Applicants respectfully request that the rejection be withdrawn.

The Examiner also alleged that no guidance is provided regarding what constitutes an active fragment of IL-27, an inactive fragment of IL-27 or guidance related to agonistic antibodies. The specification provides considerable data regarding the connection between immune suppression and the receptor for IL-27. The specification describes IL-27 as an example of an agonistic ligand to IL-27R, e.g., a ligand that enhances the activity of the receptor. Applicants claim the novel use of antibodies to IL-27R and active fragments of IL-27 to suppress the immune system. It is well known to those of skill in the art that antibodies can be made to specific proteins, e.g., the IL-27R receptor. Furthermore, one of skill in the art would be aware that fragments of proteins can retain activity, e.g., binding activity, and one of skill would be able to determine which fragments of IL-27 bind to IL-27R and enhance activity using the guidance provided. Therefore, given the skill level on the art, enough guidance is provided for one of skill to make and use the claimed invention without undue experimentation.

The Examiner also alleged that some of the disorders included in Applicants' Markush group of immune disorders are not immune disorders at all; however, no particular conditions were specified in the Office Action. Applicants herein amend the claims to specify that patients selected are those who are in need of immune suppression and that the patients treated may suffer from any of the list of diseases provided. Applicants believe the claims as amended are enabled. If the Examiner still believes that some conditions should not be listed, Applicants respectfully request that those conditions and the reason they should not be included be stated.

Applicant believes that the claims are enabled and respectfully request that the rejections be withdrawn.

35 U.S.C. §112, First Paragraph – The Written Description is Adequate.

Claims 1-26 and 73 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleged that the subject matter of the claims is not described in such a way to convey to one of skill in the art that the inventors were in possession of the invention at the time the application was filed.

"The requirement for an adequate written description ensures that the public receives something in return for the exclusionary rights that are granted to the inventor by a patent." M.P.E.P § 2162. To do so, a patentee must disclose sufficient information to put the public in possession of the invention. This requirement is met when the specification describes "the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P § 2163.

In depth support in the specification for the present invention as claimed is provided below. The written description provides support for the claims and shows that Applicant had possession of the invention at the time the application was filed. For example, a multitude of data is provided in the example section to show that WSX-1 is not needed to generate a Th1 response to infection, but rather is needed to regulate the intensity and duration of the T cell response. Applicants then go on to show, e.g., in Example 4, that hyperactivity of the immune system is caused by the lack of WSX-1. See, also, the remaining examples providing further support for the role that IL-27R plays in immune suppression. Therefore, the method is adequately described in the specification so that one of skill would know that Applicant was in possession of the invention, e.g., a method of suppressing the immune system with an agonistic ligand to IL-27R.

The Examiner alleged that Applicants claim a genus while only describing a single species within that genus. However, the species to which the Examiner refers is a method of assessing a role for WSX-1. Although Applicants describe their method for assessing the role of the IL-27R cytokine receptor, Applicants claim a method of using an

agonistic ligand to that receptor, which method of use is determined by the assessed role of IL-27R. What Applicants actually claim is a method of suppressing the immune system using a ligand to IL-27R, an example of which is IL-27. Therefore Applicants adequately describe at least one member of the genus of ligands, e.g., the IL-27 ligand.

As provided in the M.P.E.P., description of one species **can** adequately support a claim to a genus. M.P.E.P § 2163. See, e.g., *Rasmussen* 650 F.2d at 1214, "disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered." In the present invention, it is not important what ligand is used, so long as it binds to and enhances activity of IL-27R. The method as claimed does not change based on the ligand used. The specification provides an adequate description for each step in the method to allow one skilled in the art to know that Applicant possessed the invention at the time of the application.

In addition, the specification describes how to make antibodies to the receptor for use in the invention. The specification further describes, e.g., beginning on the first full paragraph on page 18 and continuing through page 20, how to identify selective binding agents including IL-27 fragments, e.g., that mimic the activity of IL-27. Specifically, page 19 describes a binding assay and suggests other binding assays, such as BIAcore and the use of immobilized solid supports and binding assays in cell cultures. The examples include, radio-immunoassays, ELISA assays and immunoprecipitation. One of skill in the art would know how to raise an antibody to IL-27R (see. e.g., page 45 of the specification) and how to identify other agents or ligands that bind thereto, including fragments of IL-27. Therefore, the specification adequately describes the compounds used in the methods of the invention.

Furthermore, the Patent Office Written Description Guidelines to which the Examiner refers, make clear, in Example 16, that an antibody claim is adequately described and enabled even when no actual antibodies are presented so long as the antigen is clearly defined. Here the antigen is IL-27R, a clearly defined cytokine receptor. The guidelines conclude that antibody structure and methods of making antibodies are well known in the art and "antibodies which bind to antigen X were implicitly disclosed as a result of the isolation

of antigen X." Therefore, the present claims are adequately described with respect to antibodies that bind to IL-27R. It is well known in the art how to raise antibodies, e.g., against a receptor. Please note that M.P.E.P § 2163 makes clear that information that is well known in the art need not be described in the specification. See also, e.g., *Hybritech, Inc., v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986).

Furthermore, Applicant reminds the Examiner that, as explained by the Federal Circuit, "(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met . . . even where actual reduction to practice is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Falkner v. Inglis* 448 F.3d 1357, 1366. (Fed. Cir. 2006). Therefore, Applicants do not have to show actual reduction to practice in the specification and is not required to provide a specific structure for any ligand, e.g., an IL-27 fragment, let alone all possible fragments that can be used in the methods of the invention. Applicants point out that the claims are drawn to a method of suppressing the immune system using a ligand to a particular receptor. Applicants do not have to provide a written description of every ligand that could possibly be used in the method. The inventive concept is that such a ligand can be used to suppress the immune system. That concept is what is presently claimed and the data provided and the specification adequately convey that the Applicants were in possession of this *claimed* invention at the time of filing.

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every possible embodiment of the claims is not explicitly described in the specification, then the adequate description requirement is met. M.P.E.P § 2163. The claimed invention is drawn to a method of treating or preventing immune disorders by suppressing the immune system with an IL-27R ligand. The specification describes the data proving that the receptor for IL-27 is directly involved with immune suppression/activation and further provides guidance on how to identify and make agonistic ligands to that receptor. The written description adequately conveys to one skilled in the art that Applicant was in possession of such a method of suppressing the immune

system at the time of filing. Applicants therefore request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

35 U.S.C. §112, Second Paragraph – The Claims are Definite.

Claims 1-26 and 73 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because of confusion regarding the terms "IL-27/WSX-1" and "IL27R/WSX-1" and the use of both the terms "agonist" and "antagonist". Applicants herein amend the claims to refer only to IL-27R and agonists thereof.

As discussed above under claim objection section, "WSX-1" is a component of the IL-27 receptor and "IL-27" is a ligand for the WSX-1 portion of the receptor. The term "IL-27/WSX-1" is used to refer to the ligand/receptor pair. Although the terms "IL-27R," "WSX-1," and "IL-27R/WSX-1" are all used in the specification to refer to a receptor for IL-27, the terms are not confusing because each is also explicitly defined in the specification and well known to those of skill in the art. Furthermore, the terms "agonist" and "antagonist" are both appropriate because agonists to IL-27R can be used to suppress the immune system and an antagonist to IL-27R is used to activate the immune system. Therefore, both agonists and antagonists are optionally used to treat immune disorders as claimed. However, to simplify prosecution, Applicants amend herein to include only the agonists used for suppression. The terms used in the claims are explicitly defined in the specification; the claims are definite and the rejection should be withdrawn.

35 U.S.C. §102.

Claims 1-26 and 73 were rejected under 35 U.S.C. §§102(a) and 102(e) as allegedly anticipated by Timans et al. Claims 1-26 and 73 were also rejected under 35 U.S.C. §102(a) as allegedly anticipated by Villarino et al. The claims were further rejected under 35 U.S.C. §102(b) as allegedly anticipated by De Sauvage et al and by Bennet at al. Claims 1-26 and 73 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Matthews et al. Applicants respectfully traverse each rejection as discussed in detail below.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. Anticipation requires that "all limitations

of the claim are found in the reference, or 'fully met' by it." Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983).

Applicants note that M.P.E.P § 706.02 states, "If the application properly claims benefit under 35 U.S.C. §119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. §112 by the provisional application." Therefore, the effective filing date of the present application is the filing date of provisional application 60/444,494, filed January 31, 2003. This is discussed in more detail in the above section regarding priority claims.

The claims are not anticipated by Timans

The Examiner rejected the claims as allegedly anticipated by Timans under 35 U.S.C. §§102(a) and 102(e). Although Timans discusses nucleic acid and protein sequences for IL-27, it only vaguely alludes to possible uses involving the immune system. In addition, the reference does not teach selecting or treating patients in need of immune suppression by activation of IL-27R. No data whatsoever is produced to show that IL-27R plays any role other than the differentiation of T cells (which was the belief prior to Applicants' invention). In the last example provided in Timans, some data is provided regarding the binding of IL-27 to WSX-1. However, the data do no more than show existence of binding and merely hint that the molecules **may** be involved with immune disfunction. See, e.g., paragraph 220. The significance of IL-27R in the suppression of the immune system is not identified. Therefore, the presently claimed use of an IL-27 receptor is not taught by Timans.

Furthermore, the focus in Timans is on the hematopoietic cells and differentiation of T cells, as that was previously thought to be the purpose or function of WSX-1 and IL-27. There is absolutely no data presented in Timans to support the newly identified role of the IL-27/WSX-1 receptor ligand pair in suppression of the immune system as presently claimed. In Timans, see, e.g., paragraphs 27-38, the primary activity of IL-27 is believed to be a differentiation role.

In addition, paragraphs 79 and 80 make clear that future studies to determine expression and control are needed as well as future studies to determine possible antagonists

and agonists for IL-27. Uses for IL-27 are discussed only in the future tense in Timans, e.g., in paragraphs 128-132, making clear that these proposed uses are conjecture only. For example, in paragraph 27, Timans states that IL-27 "may play a role in inflammation . . ." However, no data whatsoever is provided to illustrate what that role might be. Paragraph 132 discusses what the IL-27 cytokine should do or could do, but provides no enabling disclosure of the specific sort presented and claimed by Applicants.

In addition, no in vivo studies are presented to support a role for IL-27 other than what was previously considered in the art, e.g., to effect a differentiation between Th1 and Th2. Nothing in Timans indicates that a new and different use for an IL-27 receptor has been discovered or invented. Therefore, if anything, Timans merely speculates about possible uses related to the immune system but provides no data and thus is not enabled for a teaching regarding the specific use of the IL-27 receptor for immune suppression as claimed. Timans, therefore, does not teach the specific use of the IL-27 receptor as presently claimed and does not anticipate the claimed invention.

Although not particularly relevant, Applicants note that Timans claims priority back to Aug 6, 1999 through a series of continuation-in-part applications. However, Applicant would like to remind the Examiner that for a reference to claim priority to a provisional, the reference must be enabled as of that date. However, data regarding the binding of IL-27 to WSX-1 was added to the Timans application when it was filed on November 30, 2001. Therefore, for 102(e) purposes in relation to this case, Timans is not entitled to the date of the parent application because the data regarding IL-27R or the WSX-1 portion of IL-27R does not appear in the parent and was only added as of the filing date, November 30, 2001.

The claims are not anticipated by Villarino

With the corrected priority claim, Villarino is not available as a reference under 35 U.S.C. §102(a). Villarino has a publication date in November 2003. Applicants properly claim the benefit of the filing date of provisional application 60/444,494, filed January 31, 2003. Therefore the invention is not anticipated by Villarino because the invention was not "patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

The claims are not anticipated by Bennet.

Bennet, if anything, discloses a WSX cytokine receptor, but it does not teach its use in treating immune hyperactivity or suppressing the immune system through IL-27R or ligands that bind to IL-27R. Therefore, Bennet does not teach every element of the claims and cannot anticipate the claimed invention.

In Bennet, WSX-1 is used to treat a variety of diseases, none of which are inflammatory diseases of the immune system as claimed. In addition, WSX-1 is used as the pharmacological agent, not a ligand to WSX-1 or IL-27R, as presently claimed.

For example, in Bennet, the following diseases are thought to be treated using WSX: diseases characterized by a decrease in hematopoietic cells, such as anemia, thrombocytopenia, hypoplasia, disseminated intravascular coagulation, myelodisplasia, immune thrombocytopenic purpura, HIV induced ITP, and Myeloproliferative thrombocytotic diseases. See, e.g., page 41. Other contemplated, but not demonstrated uses include infertility, hypercholesterolemia, and hyerlipidemia, cardiovascular disease, and hypertension. This set of diseases and conditions does not teach treatment or prevention by immune suppression as presently claimed because Applicants' novel use for IL-27R ligands was not known at the time of the Bennet publication.

Although Bennet vaguely states that WSX may be used to induce proliferation of cells, it does not state that the cells that proliferate in response to WSX are immune cells and does not use the IL-27R receptor or its ligand, IL-27, to treat any disease related to hyperactivity of immune cells or suppression of the immune system. Bennet was unaware of the role IL-27R plays in suppression of the immune system and therefore cannot teach every element of the claimed invention.

The claims are not anticipated by Matthews

Matthews describes the use of WSX, a cytokine receptor, in enhancing the proliferation or differentiation of hematopoietic cells. WSX itself is administered to a patient in need of an increase in blood cells, sometimes with a ligand to WSX used in combination to increase the half-life of WSX. See, e.g., column 40, lines 4-31. In contrast, the present

invention claims the use of an IL-27R agonistic ligand to suppress the immune system. In Matthews, the receptor itself, not a ligand thereto, is administered to treat obesity, bulimia, and diabetes, and the like. See, e.g., column 50, lines 47-67. No patient in need of immune suppression is selected for treatment in Matthews because the role that WSX-1 plays in immune suppression was not known at the time. Therefore, Matthews does not teach suppression of the immune system as presently claimed and does not anticipate the claimed invention.

The claims are not anticipated by De Sauvage

If anything, De Sauvage teaches, as do many others, a role for IL-27R in the differentiation of Th1 and Th2 cells, not a role in general immune suppression, as presently claimed. Therefore, de Sauvage does not teach the administration of an agonistic ligand to IL-27R to a patient in need of immune suppression as presently claimed. Because De Sauvage teaches that such a ligand would alter the balance of the immune response, not the intensity or duration of the response as Applicants teach, there is nothing in De Sauvage to teach or suggest that patients in need of immune suppression be selected for treatment involving WSX-1 or IL-27R. Even if De Sauvage purports to treat immune disorders with a ligand to WSX-1, the reference is not enabled because it does not specify the correct mode of treatment or provide even one possible ligand for use in that treatment. For example, in De Sauvage a patient in need of immune suppression would not be selected as presently claimed, because the reference teaches that the WSX-1 receptor is involved in altering the balance of an immune reaction between a Th1 and a Th2 response, not in suppressing the immune system generally as claimed. Therefore, De Sauvage does not teach every element of the claimed invention and cannot anticipate the claimed invention.

Rejections under 35 U.S.C. §102 should be withdrawn

In all of the references, the most that can be said is that they teach the IL-27R receptor and its relation to IL-27 as a ligand and perhaps a role in T cell differentiation. However, what is claimed is a new use of these compounds for immune suppression. "A new use of a known composition of matter can be properly claimed only be claiming the

invention as a process or method." *Clinical Products Limited v. Brenner* 149 U.S.P.Q. 475, 477 (D.C. 1966). The present claims are method claims and therefore properly claim a new use for a known compound. To show anticipation, the Patent Office must show that the prior art teaches a connection between the IL-27/WSX-1 ligand/receptor pair and suppression of the immune system (as provided in the present application) and its use to treat related conditions. This has not been shown by any of the references and therefore, none of the references anticipate the claimed invention.

To the extent that the rejection is that Bennet, Timans, Matthews, or De Sauvage *inherently* relate to the use of WSX-1 ligands to treat immune system diseases and conditions, the Examiner is respectfully reminded that, "patentability of a new use (of an old material) based on an inherent, but previously unrecognized, property is not precluded. A contrary conclusion confuses anticipation by inherency, i.e., lack of novelty, with obviousness." *Jones v. Hardy* 220 U.S.P.Q. 1021, 1025 (Fed. Cir. 1984). Nothing in the cited prior art remotely demonstrates that WSX-1 or its ligands are directly related to suppression and/or activation of the immune system. Plainly, it was not contemplated or suggested in any of the references that ligands of IL-27R would be given to patients in need of immune suppression. Thus, the references cannot be used to establish anticipation by inherency.

None of the references cited in the Office Action teach selection of a patient in need of immune suppression for treatment with an agonistic ligand to IL-27R. Applicants therefore respectfully request that the rejections be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

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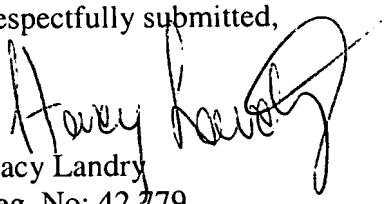
Respectfully submitted,



Stacy Landry
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Attachments:

1) A petition to extend the period of response for 3 months;
2) A transmittal sheet;
3) A receipt indication postcard.